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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/667,043

09/22/2003

Alan Eskuri

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EXAMINER

NGUYEN, HUONG Q

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

09/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/667,043	Applicant(s) ESKURI, ALAN	
	Examiner HELEN NGUYEN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 13-16, 19, 22-24, 26 and 30 is/are pending in the application.
- 4a) Of the above claim(s) 5-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 9, 11, 13-16, 19, 22-24, 26 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/21/2009 has been entered.
2. Claims 1, 13, and 22 are amended. **Claims 1-4, 8-9, 11, 13-16, 19, 22-24, 26, and 30** remain under prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. **Claims 15 and 22-26, 26, and 30** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claims 15 and 22 recite that the outside diameter of the coil is “substantially equal” to the diameter of the proximal portion of the core member. Given the broad and relative nature of the term “substantially,” this renders the claims indefinite because it is not clear if the outside diameter of the coil is or is not equal to the outside diameter of the proximal portion of the core member. The diameters are either equal, or they are not equal. They may not be both equal and unequal. Applicant is respectfully requested to amend the claims to clearly and definitely recite the desired diameter limitation.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **Claims 1, 9, and 11** are rejected under 35 U.S.C. 102(b) as being anticipated by Fujimoto et al (US Pub No. 20030181828).

7. In regards to **Claim 1**, Fujimoto et al disclose a guide wire comprising:

an elongated inner core member 2 including a proximal section 20, 21 and a distal section 22-24, the distal section including a proximal portion and a distal portion, best seen in Figure 1 and 10;

an elongated reinforcing member 35 having a proximal end and a distal end and an inner surface extending between the proximal and the distal end, the elongated reinforcing member disposed about the proximal portion of the distal section such that the distal portion of the distal section is free of the reinforcing member, best seen in Figure 10, and such that the inner surface of the elongated reinforcing member is in contact with the proximal portion from the proximal end to the distal end through fixing material 9, best seen in Figure 10;

an outer coil member 3, 4 having a proximal end and a distal end, the outer coil member disposed about the distal section of the core member, there being no intervening layer of material

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between the distal portion of the distal section of the inner core member and the outer coil member, best seen in Figure 1 and 10;

the outer coil member is located exterior of the elongated reinforcing member such that there exists an unoccupied space between the entire perimeter of the elongated reinforcing member and the outer coil member, best seen in Figure 10;

wherein the proximal end of the outer coil member is located proximal of the proximal end of the elongated reinforcing member, best seen in Figure 10.

8. In regards to **Claim 9**, Fujimoto et al disclose the core member 2 comprises stainless steel (¶0032, 0034).

9. In regards to **Claim 11**, Fujimoto et al disclose the outer coil member 3, 4 comprises stainless steel (¶0038, 0040).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **Claims 2-4** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujimoto et al in view of O'Connor et al (US Pat No. 6887235).

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12. Fujimoto et al disclose the invention above but do not expressly disclose that the reinforcing member is a tube having at least one cut or groove or is made of a nickel-titanium alloy. O'Connor et al teach a tubular reinforcing member with a helical groove (40 in figure 3A) or a plurality of cuts (44, 46 in figure 4A) made of nickel titanium alloy (Col.4: 63-64) for the purpose of providing desired torque and flexibility characteristics to the reinforcing member without requiring additional components (column 2, lines 23-26). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a nickel-titanium alloy tube having at least one helical groove as taught by O'Connor et al as a reinforcing member in Fujimoto et al in order to provide a reinforcing member with desired torque and flexibility characteristics without requiring additional components.

13. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Fujimoto et al in view of Palermo et al (US Pat No. 5769796).

14. Fujimoto et al disclose the invention above but do not explicitly disclose the distal portion of the distal section of the core member has a non-circular cross section. Palermo et al teach an analogous guide wire with a distal portion of the distal section of the core member having a non-circular cross-section (column 6, lines 63-67) as an effective construction of the distal portion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the distal portion of the core member of Fujimoto et al to have a non-circular cross section as taught by Palermo et al as an effective configuration for the guide wire with maintained the characteristic desired for its use.

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15. **Claims 13-16 and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujimoto et al in view of O'Connor et al.

16. In regards to **Claims 13 and 19**, Fujimoto et al disclose a guide wire comprising:

an elongated inner core member 2 the core member having a proximal region 20-21 and a distal region 22-24 with at least a portion of the distal region including stainless steel (¶0032, 0034), the distal region having a proximal section and a distal section, best seen in Figure 1 and 10;

an elongated reinforcing member 35 disposed about the inner core member, the reinforcing member having a proximal end and a distal end, wherein the distal end terminates proximal of the distal section of the distal region of the core member, best seen in Figure 10;

an outer coil member 3, 4 having a proximal end and a distal end, the outer coil member disposed over the distal section of the core member and at least a portion of the reinforcing member, best seen in Figure 10;

the outer coil member located exterior of the elongated reinforcing member such that there exists an unoccupied space between the entire perimeter of the elongated reinforcing member and the outer coil member, best seen in Figure 10;

wherein the proximal end of the outer coil member is located proximal of the proximal end of the reinforcing member, best seen in Figure 2.

17. However, Fujimoto et al do not disclose the elongated reinforcing member being tubular and having at least one cut or groove. O'Connor et al teach a tubular reinforcing member with a helical groove (40 in figure 3A) or a plurality of cuts (44, 46 in figure 4A) made of nickel

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titanium alloy (Col.4: 63-64) for the purpose of providing desired torque and flexibility characteristics to the reinforcing member without requiring additional components (column 2, lines 23-26). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a nickel-titanium alloy tube having at least one helical groove as taught by O'Connor et al as the reinforcing member of Fujimoto et al in order to provide a reinforcing member with desired torque and flexibility characteristics without requiring additional components while still performing its desired function.

18. In regards to **Claim 14**, Fujimoto et al disclose the distal region 22-24 of the core member 2 is stainless steel (¶0032, 0034).

19. In regards to **Claim 15**, Fujimoto et al disclose the proximal region 20, 21 of the core member 2 has a diameter and the outer member 3, 4 has an outside diameter substantially equal to the diameter of the proximal region of the core member, best seen in Figure 1 and 10.

20. In regards to **Claim 16**, Fujimoto et al disclose the outer coil member 3, 4 comprises stainless steel (¶0038, 0040).

21. **Claims 22-24, 26, and 30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shireman et al (US Pat No. 7182735) in view of O'Connor.

22. In regard to **Claims 22, 26, and 30**, Shireman et al disclose a guide wire comprising:

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an elongated inner core member 14, 16, the inner core member including stainless steel (Col.3: 51-58), the inner core member including a proximal portion 31, 33, 37 having a first cross-sectional area, an intermediate portion 39 having a second cross-sectional area, wherein the second cross-sectional area is less than the first cross-sectional area, and a distal portion 27 having a ribbon profile, best seen in Figure 1;

an elongated tubular member 65, the tubular member having a proximal end and a distal end and a length extending from the proximal end to the distal end, the tubular member being disposed about the intermediate portion of the inner core member and in contact with the intermediate portion along the length through attachment material 63, best seen in Figures 1 and 8;

a coil tip 80 including stainless steel (Col.16: 8-13), the coil tip having a proximal end and a distal end, the coil tip extending over the distal portion of the inner core member and the tubular member, best seen in Figure 1 and 8;

wherein the proximal end of the coil tip is located proximal of the proximal end of the tubular member, best seen in Figure 1 and 8;

the coil tip has an outside diameter, wherein the outside diameter of the coil tip is substantially equal to the diameter of the proximal portion of the core member configured to create a smooth transition from the core member to the coil tip, best seen in Figure 1.

23. However, Shireman et al do not explicitly disclose the elongated tubular member having at least one cut or groove. Shireman et al also teach the guide wire having tubular connector 18 having at least one cut or groove defined along its length to effectively allow the tubular connector to be bendable as well as transmit torque and pushing forces (Col.8: 32-Col.9: 57).

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Shireman et al also teaches that connector 18 may be made of any material associated with the guidewire, such as nickel titanium alloy (Col.9: 51-54; Col.3: 51-59). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the elongated tubular member of Shireman et al to have at least one cut or groove defined along its length as taught by Shireman et al to effectively allow the tubular connector to be bendable as well as transmit torque and pushing forces.

24. In regards to **Claim 23**, Shireman et al disclose at least a portion of the intermediate 39 portion and the distal portion 27 of the core member 14, 16 includes stainless steel (Col.3: 51-58).

25. In regards to **Claim 24**, Shireman et al disclose the proximal portion 31, 33, 37 of the core member 14, 16 has a diameter and the intermediate portion 39 has a diameter less than the diameter of the proximal portion, best seen in Figure 1.

Response to Arguments

26. Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736

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